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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,445	03/09/2001	Gary Van Nest	377882001300	7011
25226	7590	01/24/2006		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/802,445	<b>Applicant(s)</b> NEST ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 9-12, 14 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-12, 14, and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/17/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Currently, claims 1-4, 6, 9-12, 14, and 23-27 are pending in the application.
2. In the prior action, the Final Action mailed on April 7, 2005, claims 1-4, 6, 9-12, 14, and 23-26 were pending and rejected.

An After final amendment was submitted on October 7, 2005, followed by a Request for Continued Examination (RCE), filed on November 17, 2005. The RCE filed under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on October 7, 2005 and on November 17, 2005 have been entered.

In the After-Final submission, claims 1 and 6 were amended.

In the RCE, claim 27 was added.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on November 17, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.
4. Documents 21-25 cited in the IDS are each International Search Reports in PCT applications. The documents are not considered prior art, and consideration of these documents does not indicate consideration of the references cited therein.

***Drawings***

5. **(Prior Objection – Withdrawn)** New corrected drawings in compliance with 37 CFR 1.121(d) were required in this application for the reasons indicated in the Notice Of Draftperson's Patent Drawing Review, mailed with the action of January 2002. In view of the submission of replacement drawings on October 7, 2005, the objection is withdrawn.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection-Withdrawn)** Claims 1-4, 6, 23, and 24 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These were rejected because it is unclear how the ISS can both delay the development of the lesion and be administered to the site of the lesion. In view of the amendment to the claims requiring that the ISS is administered to the site of exposure to the papillomavirus, instead of to the site of the lesion, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection- Maintained)** Claims 1-4, 6, 9-12, 14, and 23-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Beutner, Bauman, and Yamamoto, and further in view of either of Raz et al. (U.S. patent 6,514,948), and Schwartz et al. (WO 98/55495- of record in the Feb 2002 IDS). The claims are drawn to a method for delaying the development of, or reducing the severity of, lesions caused by HPV infections through the administration of an immunostimulatory nucleic acid sequence to the site of the lesion or infection. The rejection is maintained, and extended to new claim 27.

The Applicant traverses this rejection on four new grounds. First, the Applicant notes that the Beutner reference indicates that it is was not known if the ability of the adjuvant imiquimod to induce an anti-papillomaviral response was per se due to the induction of IFN- $\alpha$ . Second, the Applicant asserts that post-filing teachings indicate uncertainty in the art as to efficacy of IFN- $\alpha$  in the treatment of papillomaviral infections. Third, the Applicant asserts that the Baumann reference teaches that IFN- $\alpha$  is only effective as an adjuvant to surgical excision. Finally, the Applicant asserts that the Yamamoto reference fails to teach that ISS induce any cytokines. These arguments are not found persuasive.

With respect to the first and third arguments in traversal, it is noted that the teachings of Baumann provide adequate grounds for a reasonable expectation of success that an adjuvant that induces IFN- $\alpha$  would be effective against HPV in view of the teachings of Baumann stating that "Single and multi-institutional studies have subsequently confirmed that  $\alpha$ -IFN decreases the growth of papillomata or increases the time interval between surgical therapies." While the

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reference indicates that IFN- $\alpha$  is used in combination with other treatments, these teachings nonetheless provide sufficient indication of the anti-papillomaviral utility of the compound for the claimed methods. In particular, it is noted that none of the present claims exclude the use of additional modes of treatment, or require that the IFN- $\alpha$  is sufficient alone to fully treat the infection. Rather, the present claims require only the ability to reduce severity or delay the formation of symptoms. The teachings of Baumann, indicating that IFN- $\alpha$  does delay or inhibition symptoms of infections (thereby permitting greater periods of time between surgical treatments) provide sufficient grounds for those in the art to have a reasonable expectation that the presence of IFN- $\alpha$  alone would be effective.

With respect to the second assertion in traversal, that the post-filing references demonstrate uncertainty, it is noted that these references relate to the treatment of other viruses, and therefore not persuasive in view of the teachings of Baumann relating specifically to papillomaviral infections.

The fourth ground of traversal, that the Yamamoto reference (alone or with the Raz and Schwartz references) does not teach that ISSs stimulate IFN-alpha production, is also not found persuasive. While Yamamoto indicates that a certain ISS sequence (that comprising ACCGGT) does not induce IFN production, it indicates that sequences comprising the sequence AACGTT (the AAC-30 sequence) do induce such production. See e.g., pages 776-777. The additional teachings of Raz and Schwartz support these teachings as previously described. The fact that Raz teaches a different method for administration is not found relevant or persuasive for the reasons indicated previously (Office action of April 2005). The fact that Schwartz teaches that an oligonucleotide comprising the ISS and encoding an antigen is not found persuasive as the

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reference indicates that the IFN-inducing activity is due to the presence of the ISS sequence (pages 4 and 29). Thus, the combined teachings of these references as previously described provide those in the art with a reasonable expectation that administration of the indicated ISS sequences would induce IFN- $\alpha$  production, and therefore be effective for delaying the development of, or reducing the severity of, symptoms of papillomaviral infections.

As the Applicant has provided no evidence demonstrating that ISSs would not be expected by those in the art to induce IFN-alpha, or that IFN-alpha production would not be expected to have the desired results, the arguments in traversal are not found persuasive and the rejection is maintained.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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11. **(New Rejection)** Claims 9-12, 14, 25, and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of copending Application No. 10/898,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the claims of the current application. The claims of the copending application are drawn to methods for reducing the recurrence of a symptom of a viral infection and to methods of reducing the severity of a viral infection through administration of an ISS. The copending application further identifies that the viral infections to be treated may be papillomaviral infections (page 5, paragraph [0055]), the site of administration (page 13, paragraphs [0132]-[0134]), and the modification of the ISS (page 9, paragraph [0101]). The present claims are drawn to species of those generic methods wherein the site of administration and the type of viral infection have been specified, such as those suggested in the specification of the copending application. Because the claims of the copending application are generic to those of the present application, and because the specific embodiments of the current application are suggested as embodiments of the generic methods in the copending application, the present claims are rejected as obvious variations thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):



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When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

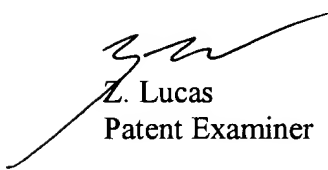
### ***Conclusion***

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

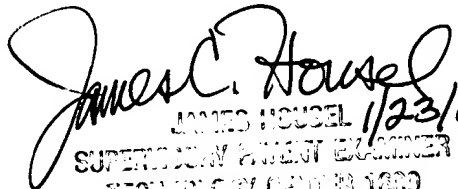
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas  
Patent Examiner



JAMES HOUSEL 1/23/06  
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